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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,763	11/12/2003	Evi Kostenis	DEAV2002/0083 US NP	8381

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EXAMINER	
PRIEBE, SCOTT DAVID	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,763	KOSTENIS ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *11-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8* is/are rejected.

7)☒ Claim(s) *1-5,9 and 10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040614*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-8 in the reply filed on 2/1/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 9 and 10 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 9 and 10, directed to the process of making or using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 11-24, directed to the invention(s) of Groups III-V do not require all the limitations of an allowable product claim, and have NOT been rejoined.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement between groups I and II as set forth in the Office action mailed on 10/20/05 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claims including all the limitations of an allowable product claim or rejoined process claim are presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are

no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 11-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/1/06. It is noted that if non-elected claims 14-16 were to be cancelled, then Group III would be limited to a combination that requires the allowable product (claim 1) as a subcombination, and would, along with group IV directed to a method of making the mammal of Group III, be rejoined with Group I/II.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/EP03/12325, filed 05/11/03. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000,

after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required.

Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

PCT/EP03/12325 has been published as WO 04/44003. However, the Examiner has been unable to obtain a copy of the WO publication, and been unable to verify that the US was a designated state in the PCT application or that the PCT application describes the same invention as instantly claimed. Applicant is requested to provide a copy of the WO document in order to determine whether the instant application is entitled to benefit of priority under 35 USC 120 and 365.

Claim Objections

Claims 1-10 are objected to because of the following informalities: Claims 1, 6, and 9 each recite "mammal". The specification (page 4, lines 2-3) explicitly defines "mammal" so as to exclude human or *Homo sapiens*. One of skill in the art reading the claims would reasonably, but incorrectly, assume that "mammal" included human. To avoid such a reasonable, but erroneous, interpretation of the claims, --non-human-- should be inserted before "mammal" in line 1 of each of claims 1 and 6, and line 3 of claim 9.

Appropriate correction is required. If corrected in claims 1 and 9, claims 1-5, 9 and 10 would be allowable. There is no suggestion in the prior art of record to transfect a myocardial cell with an adenovirus that expresses EDG2 and a cellular marker in the cell.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, specifically on products of nature. Claims 6-8 are directed to a myocardial cell that expresses EDG2 and a cellular marker. Claim 7 requires the cellular marker to be a fluorescent protein. The claims do not require the cell to be isolated, and so read on myocardial cells in a non-human mammal. The claims do not require that the EDG2 or cellular marker be exogenous to the myocardial cell. As disclosed in An et al. (Biochem. Biophys. Res. Commun. 231: 619-622, 1997, Table 1) and Goetzl et al. (J. Biol. Chem. 275(19): 14573-14578, 2000, page 14575, col. 1), EDG2 is naturally expressed in the mammalian heart (Table 1). With respect to "cellular marker," the definition of this term (spec., page 4) is operational, the marker must be a protein, and that protein must be detectable when a mammalian cell is transformed with nucleic acid encoding it. The definition does not require that the nucleic acid encoding the cellular marker actually be transformed into the claimed cell. Any protein endogenous to a mammalian myocardial cell would meet the limitation as defined. Furthermore, the term "cellular marker" is usually used in the art to refer to a protein that is expressed in a given cell type or limited set of cell types, which can be used to identify that cell type or types. With respect to claim 7, many proteins that occur in nature are fluorescent, often due to cofactors such as NAD or flavins. As disclosed in Kawada et al. (Biochem. Biophys. Res. Commun. 259: 408-413, 1999, abstract) fluorescence from one of the these protein cofactors, NADP, interferes with detection of GFP fluorescence in the mammalian heart.

For the reasons, set forth above, the claimed cell reads on a mammalian myocardial cell in a naturally occurring mammal, and is a product of nature.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawada et al. (Biochem. Biophys. Res. Commun. 259: 408-413, 1999), as evidenced by An et al. (Biochem. Biophys. Res. Commun. 231: 619-622, 1997) and Goetzl et al. (J. Biol. Chem. 275(19): 14573-14578, 2000).

Kawada describes rat myocardial cells that have been transformed *in vivo* with a vector for expression of GFP (see abstract for overview). Although expression of EDG2 in the myocardial cells is not discussed in Kawada, An (Table 1) and Goetzl (page 14575) disclose that the myocardial cells naturally express EDG2, i.e. expression of EDG2 in the myocardial cells of Kawada is an inherent characteristic.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER